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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/311,890 05/14/99 SABRY

J 19681-2

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HM12/0716

EXAMINER

MARSCHEL, A

ART UNIT

PAPER NUMBER

1631

DATE MAILED:

07/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

# Office Action Summary

Application No.  
09/311,890

Applicant(s)

Sabry et al.

Examiner

Ardin Marschel

Art Unit

1631



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Oct 3, 2000
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-44 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-44 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirements.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) (5 sheets)
- 18) ☒ Interview Summary (PTO-413) Paper No(s). 10
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: Attachment to PTO-948

Applicants' election with traverse of Group III in Paper No. 14, filed 10/3/00 (with FAX copy on 4/20/01) is acknowledged. The traversal arguments have been found to be persuasive. Therefore the restriction requirement, mailed 9/1/00, is hereby withdrawn and all presently pending claims are under examination at this time. This includes added claims 29-44, filed 8/28/00.

Applicant is hereby notified that the required timing for the correction of drawings has changed. See the last 6 lines on the sheet which is attached entitled "Attachment for PTO-948 (Rev. 03/01 or earlier)". It is noted that 29 sheets of Informal Drawings have been filed in the instant application. Due to the above notification Applicant is required to submit formal drawings within the time period set for responding to this Office action. Failure to respond to this requirement may result in abandonment of the instant application or a notice of a failure to fully respond to this Office action.

Claims 1-15 and 29-39 are rejected, as discussed below, under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1, lines 7-8, the phrase "the plate" is set forth without clear antecedent basis as to such a particular plate in prior wording in the claim. This "the plate" phrase is also in claim 11, line 5, as well as claim 29, line 6, which lacks

antecedent basis. Similarly, the phrase "the plurality of cells" in claim 1, line 8, indicates a specific plurality whereas multiple sites in lines 3-4 each with a plurality of cells indicates multiple pluralities of cells in contrast to a specific plurality in line 8. Clarification via clearer claim wording is requested. Claims dependent directly or indirectly from claims 1, 11, or 29 also contain the above unclarities due to their dependence.

Claim 3, line 3, contains the confusing internally conflicting phrase "one sub-elements" which contains the singular term "one" in contrast to the plural phrase "sub-elements. Clarification via clearer claim wording is requested.

Claim 6 is internally conflicting in that the magnification is characterized as being "1X and greater" wherein probably 1X "or" greater may have been what was meant. Claim 14 also contains this unclarity. Clarification via clearer claim wording is requested.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(e) the invention was described in a patent granted on an

application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claims 11-14 and 16-28 are rejected under 35 U.S.C. § 102(a) and (e) as being clearly anticipated by Hemstreet, III et al. (P/N 5,733,721).

Hemstreet, III et al. is a fluorescence imaging reference which goes into detail as to digital analysis of the cell images as shown, for example, in a flow charts in Figures 12A - 19B. A couple of cell images are depicted in Figures 2A and 2B. The usage of multiple cell sites or slides on a slide stage or rack is described in Hemstreet, III et al. in column 28, line 27, with these multiposition slide stages analyzed as described in column 29, lines 8-14, wherein a plurality of patient samples are analyzed for each loaded stage position. The digitization of images is described, for example, in column 29, line 63, through column 30, line 62, as well as image analysis storage and retrieval in said Figures 12A - 19B and related description. Hemstreet, III et al. lacks specifics of illumination of the microscope slide samples, but clearly must inherently illuminate them in order to determine an image. Hemstreet, III et al., however, does evaluate the samples for various criteria that are related between samples such as cancer risk assessment as described in Example 4 starting in column 32 as well as in other

such analyses thus describing the prediction module of instant claim 19 as well as a translation module for permitting said assessments. It is noted that the cells imaged by the reference include the entirety of cells as shown in Figures 2A and 2B, for example, which clearly includes known and unknown compounds which form such a complex image.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 1-6, 8-28, 40, and 42-44 are rejected under 35 U.S.C.

§ 103(a) as being unpatentable over Hemstreet, III et al. (P/N 5,733,721); taken in view of Sutherland et al. (P/N 4,818,710).

Hemstreet, III et al. is a fluorescence imaging reference which goes into detail as to digital analysis of the cell images as shown, for example, in a flow charts in Figures 12A - 19B. A couple of cell images are depicted in Figures 2A and 2B. The usage of multiple cell sites or slides on a slide stage or rack is described in Hemstreet, III et al. in column 28, line 27, with these multiposition slide stages analyzed as described in column 29, lines 8-14, wherein a plurality of patient samples are analyzed for each loaded stage position. The digitization of images is described, for example, in column 29, line 63, through column 30, line 62, as well as image analysis storage and retrieval in said Figures 12A - 19B and related description. Hemstreet, III et al. lacks specifics of illumination of the microscope slide samples, but clearly must illuminate them in order to determine an image thus motivating this practice. Hemstreet, III et al., however, does evaluate the samples for various criteria that are related between samples such as cancer risk assessment as described in Example 4 starting in column 32 as well as in other such analyses thus describing the prediction module of instant claim 19 as well as a translation module for permitting said assessments.

Sutherland et al. describes liquid analysis with waveguides including microscope slide samples as summarized in the abstract and in column 8, line 62, through column 9, line 30, wherein illumination occurs of a sample with liquid and/or index matching oil (a liquid) utilized therein. It is noted that the elements of the illuminator are separated by various distances as needed to mirrors etc. as shown in Figure 2 with will prevent vibration from being directly transferred between elements also due to a lack of contact as required in instant claims 3 and 8. Thus, the illumination includes liquid and a light guide thus describing this type of illumination as required in instant claim 1, lines 7-9, for a microscope slide sample.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to practice the Hemstreet, III et al. digital imaging of multiple slide samples with the liquid light guide slide illumination system of Sutherland et al. since Hemstreet, III et al. motivates illumination in order for fluorescence to be measured as desired from the prior art of which Sutherland et al. contains such a illumination description thus resulting in the practice of the instant invention.

Claims 1-44 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hemstreet, III et al. (P/N 5,733,721); taken in view of Sutherland et al. (P/N 4,818,710); taken further in view



of either of Balch(P/N 6,083,763) or In re Venner (120 USPQ 193); all before taken in view of Rutenberg et al.(P/N 5,287,272) for barcode practice.

This rejection is directed to claim embodiments wherein the usage of robotic arms in assay sample manipulation. The above combination of Hemstreet, III et al. in view of Sutherland et al. has been summarized above but lacks automation such as the use of a robotic arm for slide or sample manipulation or 96 well samples such as microtiter plate usage.

Balch describes the use of robotic arms for moving samples during sample preparation during assays including 96 well microtiter plate assays. See Figures 1 and 4, for example, for 96 or more well plates manipulated with a robotic arm. Robotic manipulation of samples for assays, including CCD camera image usage as is also well known in the art, is described in column 6, lines 25-34. Alternatively, the automation of a manual method is deemed obvious as supported by the legal decision of In re Venner (120 USPQ 193).

Additionally, the use of barcodes on assay items such as microscope slides is motivated and suggested by well known barcode usage in the world as well as in Rutenberg et al. at column 10, lines 39-52, or column 12, lines 3-18.

Thus, it would have been obvious to someone of ordinary skill in the art at the time of the instant invention to automate

the manual procedures of Hemstreet, III et al. in view of Sutherland et al. given the motivation and usage of such automation for material handling during assay procedures as set forth in Balch or legally made obvious by In re Venner thus resulting the practice of the automated robotic arm embodiments of the above listed instant claims. The additional barcode limitation in instant claim 41 is suggested and motivated for assay items in the instant invention by combining Rutenberg et al. with the above references as stated above.

On the enclosed PTO Forms 1449 several citations directed to provisional applications have been lined through because they do not have a date of publication as required for citations of said forms. They, however, have been considered.

The disclosure is objected to because of the following informalities:

In the specification on page 1, several blanks need to be filed in with Serial numbers. Pages 7 and 45, lines 32 and 27, respectively, also contains such an unfilled in blank line.

In the specification on page 6, the Brief Description of the Drawings is insufficient. A separate brief description of each drawing is required. It is noted that Figures 3-6, 18, and 19 are not separately briefly described. Also, subpart Figures need to be separately identified and described. It is noted that such subpart drawings are present as Figures 5A and 5B but not

described on said page 6.

In claim 8, line 1, the phrase "guide characterized" seems to be awkwardly worded and maybe should be considered as missing an "is" therein. Similarly, claim 18, line 6, seems to lack the word "of" or "for" after the phrase "spatial value".

Correction is required.

No claim is allowed.

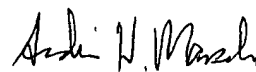
Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703)308-4242 or (703)305-3014.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ardin Marschel, Ph.D., whose telephone number is (703)308-3894. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703)308-4028.

Any inquiry of a general nature or relating to the status of this application should be directed to Patent Analyst, Tina Plunkett, whose telephone number is (703)305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

July 13, 2001

  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER